Minneapolis Fire Department

Interoffice Communication

To: Connie Beck
Marie Swerdfiger

From: Chief Forte'
Assistant Chief Seal
Deputy Chief Holt

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Subject: Automatic External Defibrillator Bids

The American Heart Association has done an excellent job in educating the public to strengthen the "Chain of Survival" by decreasing the time from cardiac arrhythmia (Ventricular Fibrillation) to treatment (defibrillation). They have accomplished this on many fronts but the most influential has been through advocacy and lobbying for legislative endorsements mandating semi-automatic defibrillators or AED's be carried for example on airplanes or placed in all federal buildings.

These mandates and increased consumer awareness have created a new market within the AED industry known as Public Access Defibrillators (PAD). Many new start-up companies have moved into the marketplace, making the competition fierce as evidenced by the diversity of products and legal battles as a result of various patent infringements. Writing a specification that is all-inclusive while trying to purchase a device that addresses the needs of the Minneapolis Fire Department as "professional rescuers" is not desirable or practical.

There are several different types of defibrillators. On the low-end cost and available options of defibrillators, you will find the new devices known as Public Access Defibrillators (PAD). These devices are designed for the lay public. PAD defibrillators are basic shock boxes, designed to lead "anyone" through a series of visual and audio prompts to deliver a shock. They have little if any fail-safes or built in self-tests and their batteries are considered one-time use only. These devices are really made for rare or occasional use and designed for use by the untrained public. An example of a PAD defibrillator is Zoll's AED Plus (price range $1,000.00-$1,200.00).

The mid-range cost and available options of defibrillators consists of AED's designed for the Basic Life Support (BLS) "professional rescuer" such as Minneapolis firefighters or police officers. This group of defibrillators must be capable of heavy day-in-day out use (MFD runs 24,000 EMS calls a year and our defibrillators go in on every EMS call). In addition the defibrillators utilized by the Minneapolis Fire Department have to be rugged enough to operate on the fire ground as they are used to resuscitate fire victims or firefighters that may go down in the line of duty. These defibrillators must be rugged, durable and they must be capable of self-checks or fail-safes and allow physician medical directors the ability to monitor or change shock energy levels or heart activity detection rates. Usually the batteries that operate these mid-range devices are capable of a range of 150-300 shocks. The most common BLS defibrillators are Philips FR2, Medtronic's Lifepak 500, and Cardiac Science's Powerheart (price range $1,900.00-$2,400.00). The new

CardioSystems Access device is attempting to be considered part of this mid-range group, although it lacks of a number of self-tests and its one-time use battery, make it a PAD defibrillator.

The upper-range cost and available option of semi-automatic defibrillators will find the devices with oscilloscopes and that are capable of manual overrides that will allow Advanced Life Support (ALS) Paramedics the ability to treat a variety of cardiac arrhythmia's. An example of an upper level defibrillator is MRL's LifeQuest ($3,400.00-$3,900.00). CardioSystems does offer an Access ALS device but that device is not represented in their bid.

Each of the AED bids has been thoroughly reviewed. The specifications include 9 requirements requested by our Medical Director, Dr. Brian Mahoney and 28 Minneapolis Fire Department requirements based upon internal data requirements and departmental limitations. The Minneapolis Fire Department reviewed 5 AED devices (Cardiac Science, Access, Philips, MRL & Lifepak 500) and received 3 AED Bids (Cardiac Science, Access & Philips) from the reviewed vendors.

It is possible that Medtronic (Lifepak 500) did not bid based on issues involving the Minneapolis Fire Department's inability to currently utilize their data download options. The MRL (LifeQuest) AED would have met each of the bid specifications (except for the daily electrode check-see explanation below). They did not bid based on its Advanced Life Support (ALS) capabilities (including a manual override) and its high per unit cost ($3,400.00-$3,900.00). Additionally, there are concerns about loosening and losing this device's battery which doubles as it's handle and that their data card was stored open in front of the device. The AED vendor, Zoll, did submit a bid. Their device was initially evaluated by the Minneapolis Fire Department and eliminated as it was designed more as a public access defibrillator and not for the professional rescuer. The Zoll unit had durability concerns, a removable cover that would be easily lost, and battery configuration, usage and operating design issues that made the unit a poor choice for the type of service required by the Minneapolis Fire Department.

Of the total 37-bid specifications, Cardiac Science met all of the specifications, Access met 32 of 37, Philips met 30 of 37 and Zoll met 24 of 37 specifications The attached line-by-line spreadsheet outlines compliance by each bidder. Of the 9 Medical Director's requirements, Cardiac Science met all of the required specifications, Philips met 5 of 9 and both Access & Zoll met 8 of 9 bid specifications.

Only 1 vendor, Cardiac Science met all 37-bid specifications. One of the 37 bid specifications is a requirement for pre-connected electrodes that perform a daily self-check. The Minneapolis Fire Department Medical Director, Dr. Mahoney, felt this specification was important to include in the bid specifications because the act of automatically checking the functioning of an AED's electrodes decreases the City's liability and just as importantly, the patient's chance for a malfunction. No other device currently performs this "functional" self-test.

It is the recommendation of the Minneapolis Fire Department that it purchase the Cardiac Science Automatic External Defibrillator. Cardiac Science is the lowest responsible bidder. This is due to other companies not submitting bids for competitive reasons. The Philips device was not included in the review because they failed to submit a device for review as specified in the bid and they only meet 5 of the 9 critical criteria established by our Medical Director. Dr. Mahoney was clearly

adamant about any device purchased utilize an escalating energy waveform. The Philips device is the only device on the market that uses a non-escalating energy waveform.

The Minneapolis Fire Department is recommending the City award the bid to Cardiac Science based on the following facts:

- Cardiac Science self tests pre-connected electrodes, electronics, and the battery daily. Access does not pre-connect the electrodes or test them. Access will alarm when the electrodes are due to expire but only if you program in the expiration date with every electrode change. Zoll pre-connects their electrodes but does not test them.

- Cardiac Science has a battery capable of 300 charges that has a memory chip, which contains a complete history of that battery. Their battery also has redundant battery cells that can allow the device to function even if a battery cell fails. Once a month their device automatically does a full-energy charge. Access does not do an automatic full-energy charge and you must manually program the AED when the battery is installed. The Access battery is considered a one-time use battery. Zoll uses commercial batteries that must be purchased from a specific manufacturer. Zoll has a red button that must be pushed when the batteries are replaced and if the button is pushed without replacing the batteries, the device will still think it has new batteries, regardless of the battery condition. Zoll only will do a 2-joule energy test.

- The Cardiac Science unit does a daily automatic self-test of the electronics, electrodes, and battery. In addition the Cardiac Science unit does a weekly charge of each including the charging circuitry and a monthly full-energy charge cycle. Access does do a daily test of electronics, but no weekly or monthly test and no circuitry charge test. Zoll does no daily test, it weekly checks electronics and electrode presence but not functionality and a 2-joule circuitry charge. Zoll does no monthly checks.

- Cardiac Science is an established company. We have done business with them for almost 6 years and their service has been impeccable. Access is a new start up company and received the worst credit rating allowed in the Dun & Bradstreet report. Both Access and Zoll (while an established company) experienced a product recall of their device in 2002.

- Cardiac Science currently has pediatric electrodes available. At present both Access and Zoll do not have FDA approval for pediatric electrodes.

The differences between the devices are substantial. The Cardiac Science Powerheart clearly meets or exceeds all the specifications compared to the rest of the devices. The most prominent features that are different are safety features that will decrease the chances of a malfunction of the unit.

Contact was made to 4 of the Fire Departments listed by Access as references. While each one liked the size of the Access device, only 1 department had seen any use and 3 had experienced a recall. Of the 1 Fire Department that had used the device 8 times (we average 160-170 uses a year), they did not like the download software. They also did not like the fact

that the electrode cable does not “click-in”. In addition they also had 1 rescue where the device had to be sent back in to justify the appropriateness of its actions. While the price and size of this device appear attractive, this AED seems best suited for the rare but occasional use.

Contact was made to 3 fire department references provided by Zoll who use their AED Plus. Of these, 1 fire department purchased 22 devices which have been in-service for 1 year with no AED uses to date. Each of the 22 devices are in-service in District Cars, Staff Cars and/or used for special event coverage only and not subject to the rugged use of fire apparatus response. The second fire department contacted had 10 devices, 7 were assigned to Engine Companies, 2 were on Squads and 1 was a training loaner unit. They felt the data, once downloaded, was clear and concise but that they had difficulties getting the data to download correctly. Additionally, they felt the data download was not user friendly. This is due to the fact the device does not store more than one run at a time. Once the unit is used it must be brought to their training facility where it is traded for a clean device, until the data on the "full" unit can be downloaded or else they run the risk of losing data. Clearly this device is an occasional use defibrillator. The Minneapolis Fire Department often will run back-to-back medical runs with full cardiac arrests with AED uses and this device will not support this type of heavy use.

Given the wide-disparity of products in the fiercely competitive AED industry, this bid specification is designed to provide an AED that will meet the rigorous needs of the Minneapolis Fire Department. The specifications are based on our Department’s needs and our patient’s best interests. It is the Minneapolis Fire Department’s recommendation that Cardiac Science be awarded the bid for automatic external defibrillators.